SPECIAL 510(k)
Device Modification Decision Summary

To: Remel Inc. **RE:** K131804

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II device requiring 510(k). The following items are present and acceptable

1. The name and 510(k) number of the SUBMITTER'S previously cleared device:

   Trade Name: Remel Xpect® Flu A&B

   510(k) number: K031565, K092423

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling.

3. A description of the device **MODIFICATION(S).** The modification presented in this 510(k) is the inclusion of the H7N9 influenza A virus strain A/Anhui/1/2013 to the analytical sensitivity information. The submitter tested the ability of the Remel Xpect® Flu A&B Test to detect the H7N9 influenza A virus. The viral stock (A/Anhui/1/2013) was obtained from the Centers for Disease Control and Prevention. It was diluted, tested in triplicate and the analytical sensitivity was reported as the lowest dilution/concentration of the H7N9 virus that the Remel Xpect® Flu A&B Test was able to detect. An LoD study was performed with the A/Anhui/1/2013 influenza strain at the following concentrations:

   - 1.26×10^6 $TCID_{50}$/mL
   - 1.26×10^5 $TCID_{50}$/mL
   - 1.26×10^4 $TCID_{50}$/mL
   - 1.26×10^3 $TCID_{50}$/mL
   - 1.26×10^2 $TCID_{50}$/mL
   - 1.26×10^1 $TCID_{50}$/mL
   - 1.26×10^0 $TCID_{50}$/mL

   The LoD was determined to be 1.26×10^5 TCID50/mL.

   The Remel Xpect® Flu A&B Test package insert has been updated to include the additional analytical sensitivity information.

4. The **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

5. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, and physical characteristics:

Similarities

Device Characteristics	Predicate Device: Remel Xpect® Flu A&B Test (K031565, K092423)	New Device: Remel Xpect® Flu A&B Test (K131804)
Intended Use	REMEL Xpect® Flu A&B is a rapid *in vitro* immunochromatographic test for the direct, qualitative detection of influenza A and influenza B viral antigen (nucleoprotein) from nasal wash, nasal swab, and throat swab specimens from symptomatic patients. The test is intended as an aid in the rapid diagnosis of influenza A and influenza B viral infections. Negative tests should be confirmed by cell culture.	REMEL Xpect® Flu A&B is a rapid *in vitro* immunochromatographic test for the direct, qualitative detection of influenza A and influenza B viral antigen (nucleoprotein) from nasal wash, nasal swab, and throat swab specimens from symptomatic patients. The test is intended as an aid in the rapid diagnosis of influenza A and influenza B viral infections. A negative test is presumptive and it is recommended these results be confirmed by virus culture or an FDA-cleared influenza A and B molecular assay.
Sample	Qualitative; Influenza A and B viral antigens with differentiation	Qualitative; Influenza A and B viral antigens with differentiation
Test Methodology	Immunochromotographic membrane assay	Immunochromotographic membrane assay
Specimen Type	Nasal wash, nasal swab, and throat swab specimen	Nasal wash, nasal swab, and throat swab specimen
Interpretation	Visual read	Visual read
Incubation	15 minutes	15 minutes

Differences

The package insert has been updated to include detection of the following H7N9 virus in the analytical sensitivity information section:

A/Anhui/1/2013(H7N9)**

**Although this test has been shown to detect the influenza A/California/04/2009 (H1N1) and A/Anhui/1/2013 (H7N9) viruses cultured from positive human specimens. The performance characteristics of this device with human specimens infected with these influenza viruses have not been established. Xpect® Flu A&B can distinguish between influenza A and B viruses, but it does not differentiate influenza subtypes.

(Note: A/Californial04/2009** was added in 2009, K092423-Special 510(k))

6. **Design Control Activities Summary**:

Summary:

1. The Xpect Flu A&B Test device design has not been modified in any way. New Analytical Sensitivity testing was performed and resulting data is submitted with this Special 510(k) application demonstrating ability of the device to detect the novel influenza A/Anhul/112013 (H7N9) virus cultured from positive human specimens. No performance characteristics were

established, modified, or removed based on this analytical testing. The intended use for this device has not changed.

2. The method used for the Risk Analysis for the Xpect Flu A&B test was Failure Mode Effects Analysis (FMEA). The methods of risk analysis were consistent with 21 CFR 820.30. The following table summarizes the risk analysis:

Modification	Hazard	Cause/s	Effect/s
Addition of H7N9 Influenza A strain: A/Anhui/1/2013	Environmental Contamination	Improper sterilization of specimens, containers, and test devices after use	Risk of disease associated with microbial hazards
	False Positive	Improper specimen transport and handling, failure to follow procedure for use, improper test interpretation Non-specific binding due to antigens in host samples other than influenza	Potential side effects of antiviral therapy, unnecessary patient isolation, inappropriate patient management
	False Negative	Poor quality of specimen collected, stage of illness, infecting subtype, improper transport, failure to follow procedure for use, improper test interpretation, Improper storage, use beyond expiration date, compromised during shipping/storage/use Manufacturing processing breach, mishandling by end-user Infecting subtype has nucleoprotein not detected or below the limit of detection of the assay	Potential lack of infection control, unnecessary antibiotic use, inappropriate management of patients with underlying conditions or those with an increased risk of serious complications

   a. For environmental hazards risk types, the effects of these common device risks were addressed with labeling and industry standards for disposal of biological and environmental waste (either bi-products or actual devices). The risks were deemed reduced to acceptable levels based on federal, state, and local regulations.

   b. For false positive and false negative test results, the effects of the risks to patients were addressed through labeling, training for users, internal and external quality control, and recommendation that negative results be confirmed by virus culture or an FDA-cleared influenza A and B molecular assay. Complaint investigations and associated trend analysis are used on an ongoing basis to evaluate overall residual risk.

3. Declaration of Conformity to Design Control

A "Declaration of Conformity" statement was submitted for the manufacturing facility and validation activities and signed by the Senior Manager Regulatory Affairs, Americas. The statements indicate that;

1. All verification and validation activities, as specified In the Risk Analysis, were performed by designated individuals and the results demonstrate that the predetermined acceptance criteria were met.
2. Remel lnc., as the manufacturing facility, is in conformance with the design control procedures stated in 21 CFR Parts 820.30. Remel lnc. has established and maintains procedures to control the design of the device and ensures that specified design requirements are met through design planning, design input and output, design review and verification, design validation, design change evaluation, and design history file.

In conclusion, based on both the results of the analytical sensitivity testing and the risk management report, the modified labeling is truthful and accurate. The changes do not affect the performance of the test and it is therefore substantially equivalent to the current cleared test.

7. A **Truthful and Accurate Statement**, a **510(k) Summary**, and the **Indications for Use Enclosure**.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. On this basis, I recommend the device be determined substantially equivalent to the previously cleared device.